GREAT SHIPS INITIATIVE (GSI) STANDARD OPERATING PROCEDURE (SOP) DEVIATION FORM

DATE/TIME: 8/26/2009 to 9/1/2009 (Form Completed 10/27/2009)
TEST ID NUMBER: 09-SI-1 and 09-SI-2 (Calibration Trials)
RDTE FACILITY OR BENCH-SCALE TESTING? Research, Testing, and Evaluation Facility Test
GSI RESEARCH TEAM MEMBER NAME/TITLE: Kelsey R. Prihoda, GSI Assistant QA/QC Officer

Deviation Number	Description of Deviation (Include SOP Number and Title)	Detailed Description of Impact on Study (If Any)	Description of Corrective Actions Taken (If Needed)
1	SOP No.: GSI/SOP/BS/RA/MA/1 – Procedure for Quantifying Heterotrophic Plate Counts (HPCs) using IDEXX's SimPlate for HPC Method. Section "Sample Collection" ¶2 Microbial samples collected from Trials 1 and 2 (Ts) and analyzed for Heterotrophic bacteria were not neutralized prior to analysis. Samples must be neutralized at the time of sample collection or when a defined exposure period has been reached (i.e., sodium thiosulfate to neutralize chlorine).	The impact of this deviation on the Calibration Trials (Trials 1 and 2) is that the post-treatment (T) heterotrophic bacteria results may not be valid due to potential exposure to active substance for greater than 48 hours after sample collection. Although the samples were exposed to active substance for up to 48 hours, the samples were diluted for analysis resulting in an active substance concentration that was at least 2 times lower in the diluted samples than the concentration at the time of collection.	No corrective action was taken at the time of the deviation. Samples analyzed for heterotrophic bacteria were treated with sodium thiosulfate upon receipt in the laboratory to neutralize the active substance during Trials 3-7.

GSI Research Team Member Comments: No further comments regarding this deviation.

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Great Ships Initiative

GREAT SHIPS INITIATIVE (GSI) STANDARD OPERATING PROCEDURE (SOP) DEVIATION FORM

DATE/TIME: 8/26/2009 to 9/1/2009 (Form Completed 10/27/2009)
TEST ID NUMBER: 09-SI-1 and 09-SI-2 (Calibration Trials)
RDTE FACILITY OR BENCH-SCALE TESTING? Research, Testing, and Evaluation Facility Test
GSI RESEARCH TEAM MEMBER NAME/TITLE: Kelsey R. Prihoda, GSI Assistant QA/QC Officer

Deviation Number	Description of Deviation (Include SOP Number and Title)	Detailed Description of Impact on Study (If Any)	Description of Corrective Actions Taken (If Needed)
1	SOP No: GSI/SOP/LB/RA/SA/1 – Procedure for Algae/Small Protozoan Sample Analysis Section "QA/QC" ¶13. There was no QA count conducted during the Calibration Trials (Trials 1 and 2). The QA count should be performed on at least 10% of samples, or at least once per trial for trials having less than ten samples, to provide consistency and replicability of assessment methods and taxonomy.	There is no impact on Trials 1 and 2 as a result of this deviation. A QA count was done on at least one phytoplankton sample from each of Trials 3-6. The raw counts and QA counts were performed by the same scientists for each analysis and the average ± standard deviation percent similarity was 85% ± 1.8%. Therefore, it can be assumed that operator bias was acceptable for Trials 1-7.	No corrective action was taken as a result of this deviation.

GSI Research Team Member Comments: No additional comments regarding this deviation.

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GSI Principal Investigator Comments:

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GREAT SHIPS INITIATIVE (GSI) STANDARD OPERATING PROCEDURE (SOP) DEVIATION FORM

DATE/TIME: 8/31/2009 (Form Completed 10/27/2009)
TEST ID NUMBER: 09-SI-1
RDTE FACILITY OR BENCH-SCALE TESTING? Research, Testing, and Evaluation Facility Test
GSI RESEARCH TEAM MEMBER NAME/TITLE: Kelsey R. Prihoda, GSI Assistant QA/QC Officer

Deviation Number	Description of Deviation (Include SOP Number and Title)	Detailed Description of Impact on Study (If Any)	Description of Corrective Actions Taken (If Needed)
1	SOP No: GSI/SOP/BS/RA/RT/6 – Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to *Ceriodaphnia dubia*. Section "Test Procedure", ¶11. *C. dubia* were fed half the required volume (0.1 mL) of Yeast-Cereal Leaves-Trout Chow suspension (YCT) and *Selenastrum capricornutum*. Each feeding must consist of 0.2 mL Yeast-Cereal Leaves-Trout Chow suspension (YCT) and 0.2 mL *Selenastrum capricornutum* concentrate/30 mL exposure solution (to provide 2-2.3 x 105 cells/mL).	There is not an impact on Trial 1 *C. dubia* WET Test as a result of this deviation. This test met the test acceptability criteria for *C. dubia* as set by the US EPA.	No corrective action was taken at the time of the deviation. The correct volume of YCT and *S. capricornutum* were fed to *C. dubia* during Trials 4-7.
2	SOP No: GSI/SOP/BS/RA/RT/8 – Procedure for Assessing Chronic Residual Toxicity of a Ballast Water Treatment System to the Green Alga (*Selenastrum capricornutum*; DRAFT). Section "QA/QC", ¶4. There was no QA count conducted during the *S. capricornutum* WET Test. A QA count of the algae cell concentration in at least 10 % of the test chambers must be performed during every trial.	The impact on Trial 1 WET Testing as a result of this deviation is that there is no measurement of operator/counting bias for the *S. capricornutum* WET Test.	No corrective action was taken at the time of deviation. It will be important to conduct QA counts on *S. capricornutum* WET Tests in the future in order to determine an acceptable level of bias.

3	SOP No.: GSI/SOP/BS/RA/RT/[illegible] – Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to the Fathead Minnow (*Pimephales promelas*), Section: Test Procedure, ¶7. Fathead Minnows were fed three times on test renewal day 3. Fatheads should be fed twice daily at 6-hour intervals. Larvae are fed approximately 0.1g of a concentrated solution of less than 24-hour old brine shrimp (*Artemia spp.*).	There is not an impact on the [illegible] *P. promelas* WET test as a result of this deviation. The additional feeding did not impact the water quality in the test chambers. This test met the test acceptability criteria for *P. promelas* as set by the US EPA.	No corrective action was taken at the time of the deviation.

GSI Research Team Member Comments: No additional comments regarding WET Testing SOP Deviations.

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GSI Co-Lead On-Site Investigator Comments:

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GSI Principal Investigator Comments:

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